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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,433	DOXSEY, STEPHEN J.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to nucleic acids, classified in class 536, subclass 23.1.

II. Claims 5-10, drawn to polypeptides, classified in class 530, subclass 300.

III. Claims 11-16 and 20, drawn to methods of reducing cell division comprising administration of nucleic acid centriolin modulators, classified in class 435, subclass 91.31.

IV. Claims 11, 17-20, drawn to methods of reducing cell division comprising administration of antibody centriolin modulators, classified in class 530, subclass 387.1.

V. Claims 21-26, drawn to methods of reducing cell division comprising the administration of nucleic acid pericentrin-B modulators, classified in class 435, subclass 375.

VI. Claims 21, 27-30, drawn to methods of reducing cell division comprising the administration of antibody pericentrin-B modulators, classified in class 424, subclass 9.1.

VII. Claim 31, drawn to methods of treating abnormal centrosome function comprising administration of centriolin, classified in class 514, subclass 1.

VIII. Claim 32, drawn to methods of treating abnormal centrosome function comprising administration of pericentrin-B, classified in class 514, subclass 2.

Applicants are also required to elect a single oligonucleotide and corresponding SEQ ID No. with the elected Group from claims 14 or 24.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to chemically, biologically, structurally and functionally distinct compounds. The nucleic acid of Group I is not needed to make the polypeptide of Group II, which could be purified from biological sources. Likewise, the polypeptide of Group II is not needed to make the nucleic acid of Group I. The searches required for proper examination of each distinct group are not coextensive: A search of the nucleic acid of Group I would not be coextensive with the search required for the polypeptide of Group II, although the searches may be overlapping.

Inventions III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different methods that result in different biological properties or

functions: methods to reduce cell division comprising administration of nucleic acids (Group III) or antibodies (Group IV) that are centriolin modulators; methods to reduce cell division comprising administration of nucleic acid pericentrin-B modulators (Group V) or antibodies pericentrin-B modulators (Group VI); methods of treating abnormal centrosome function comprising administration of centriolin (Group VII) and methods of treating abnormal centrosome function comprising administration of pericentrin-B (Group VIII). Each method involves either monitoring for a distinct function or biological effect, or different and distinct methods steps (e.g. comprising administration of different and distinct compositions) and therefore each Group comprises different assay or active steps, each examining a different biological outcome. In addition, the transformation of the different and distinct nucleic acid or protein compositions comprises different and distinct methods steps. The searches required for proper examination of each distinct group are not coextensive, although some searches may be overlapping.

Inventions of Groups I-II and III-VIII are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions of Groups I and II are not required for the methods of Groups III-VIII. The compositions and steps used in one Group's methods are not required or used in another Group's methods. A search of one Group's methods and steps would not be coextensive with the proper search required for the other Groups' methods and a search of more than

one patentably distinguishable group would not be coextensive with a proper search required for the other groups. For these reasons, the inventions of these different and distinct Groups are capable of supporting separate patents.

Claims 11 and 21 link(s) the various inventions (of Groups III-VI). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 11 and 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The different inventions drawn to each oligonucleotide SEQ ID NO. are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oligonucleotides and methods comprising them are biologically, structurally and functionally different and distinct from each other. The methods involving the use of a

distinct oligonucleotide utilize a different and distinct composition, and so utilize distinct methods steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Furthermore, searching the inventions of Groups comprising all of these different oligonucleotide molecules and target genes, and the methods comprising them together would impose a serious search burden. In the instant case, the search of the distinct methods and compositions are not coextensive. There is a search burden also in the non-patent literature. Prior to the concomitant construction and utilization of the different nucleic acid constructs of interest there may be journal articles devoted solely to one Group that would not have described the compositions and methods of the other Group. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of the different Groups together.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods comprising administration of different nucleic acid oligonucleotides are unrelated as they comprise distinct steps and utilize different nucleic acid constructs which demonstrates that each method has a different mode of operation. The methodology and materials necessary for each of these distinct methods differ significantly, and each Group constitutes a biologically, chemically and functionally distinct and different composition and method and therefore each involves a patentably distinct invention. Therefore,

each method is divergent in materials and steps. For these reasons the inventions of these different Groups are patentably distinct.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different oligonucleotides and target genes, and their corresponding SEQ ID Nos. listed in claims 14 and 24, and encompassed by claims 11-16 and 21-26 are subject to restriction. In the instant case, one independent and distinct oligonucleotide sequence will be examined in a single application without restriction. Those sequences which are patentably indistinct from the sequence or region selected by the applicant will also be examined.

Claims 14 and 24 specifically embrace different oligonucleotides and target genes with different SEQ ID Nos. Each of these oligonucleotides and corresponding genes is considered to be structurally independent, because each is represented by a unique nucleotide sequence. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark Office to search and examine. In view of the foregoing, applicants are required to elect up to 1 oligonucleotide (SEQ ID No.) and corresponding target sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the

status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
4-17-06

TC 1600

JANE ZARA, PH.D.
PRIMARY EXAMINER